

CMS Library
C2-07-13
7500 Security Blvd.
Baltimore, Maryland 21244

I

106TH CONGRESS
1ST SESSION

H. R. 1057

To provide individuals with access to health information of which they are a subject, ensure personal privacy with respect to health-care-related information, impose criminal and civil penalties for unauthorized use of protected health information, to provide for the strong enforcement of these rights, and to protect States' rights.

IN THE HOUSE OF REPRESENTATIVES

MARCH 10, 1999

Mr. MARKEY (for himself, Mr. McDERMOTT, Mr. FROST, Ms. KAPTUR, Mr. MOAKLEY, Ms. ROYBAL-ALLARD, Mr. NADLER, Mr. FRANK of Massachusetts, Mr. CROWLEY, Mr. GREEN of Texas, Mr. MCGOVERN, Mr. LUTHER, Mr. SANDERS, Mr. MASCARA, Mr. BROWN of California, Mr. ROMERO-BARCELÓ, Mr. DELAHUNT, Mr. DEFazio, Mr. CAPUANO, Mr. STARK, Mr. STRICKLAND, and Ms. LOFGREN) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide individuals with access to health information of which they are a subject, ensure personal privacy with respect to health-care-related information, impose criminal and civil penalties for unauthorized use of protected health information, to provide for the strong enforcement of these rights, and to protect States' rights.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Medical Information Privacy and Security Act”.

4 (b) TABLE OF CONTENTS.—The table of contents for
5 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purposes.
- Sec. 4. Definitions.

TITLE I—INDIVIDUALS’ RIGHTS

**Subtitle A—Access to Protected Health Information by Subjects of the
Information**

- Sec. 101. Inspection and copying of protected health information.
- Sec. 102. Supplements to protected health information.
- Sec. 103. Notice of privacy practices.

Subtitle B—Establishment of Safeguards

- Sec. 111. Establishment of safeguards.
- Sec. 112. Accounting for disclosures.

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. Authorizations for disclosure of protected health information for treatment and payment.
- Sec. 203. Authorizations for disclosure of protected health information other than for treatment or payment.
- Sec. 204. Emergency circumstances.
- Sec. 205. Public health.
- Sec. 206. Protection and advocacy agencies.
- Sec. 207. Oversight.
- Sec. 208. Disclosure for law enforcement purposes.
- Sec. 209. Next of kin and directory information.
- Sec. 210. Health research.
- Sec. 211. Judicial and administrative purposes.
- Sec. 212. Individual representatives.
- Sec. 213. Prohibition against retaliation.

**TITLE III—OFFICE OF HEALTH INFORMATION PRIVACY OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Subtitle A—Designation

- Sec. 301. Designation.

Subtitle B—Enforcement

CHAPTER 1—CRIMINAL PROVISIONS

Sec. 311. Wrongful disclosure of protected health information.

Sec. 312. Debarment for crimes.

CHAPTER 2—CIVIL SANCTIONS

Sec. 321. Civil penalty.

Sec. 322. Procedures for imposition of penalties.

Sec. 323. Civil action by individuals.

TITLE IV—MISCELLANEOUS

Sec. 401. Relationship to other laws.

Sec. 402. Effective date.

1 SEC. 2. FINDINGS.

2 The Congress finds as follows:

3 (1) Individuals have a right of privacy with re-
4 spect to their protected health information and
5 records.

6 (2) With respect to information about medical
7 care and health status, the traditional right of con-
8 fidentiality (between a health care provider and a
9 patient) is at risk.

10 (3) An erosion of the right of privacy may re-
11 duce the willingness of patients to confide in physi-
12 cians and other practitioners and may inhibit pa-
13 tients from seeking care.

14 (4) An individual's privacy right means that the
15 individual's consent is needed to disclose his or her
16 protected health information and that the individual
17 has a right of access to that health information.

18 (5) Any disclosure of protected health informa-
19 tion should be limited to that information or portion

1 of the medical record necessary to fulfill the imme-
2 diate and specific purpose of the disclosure.

3 (6) Health research often depends on access to
4 both identifiable and de-identified patient health in-
5 formation and health research is critically important
6 to the health and well-being of all people in the
7 United States.

8 (7) The Supreme Court found in *Jaffee v.*
9 *Redmond* (116 S.Ct. 1923 (1996)) that there is an
10 imperative need for confidence and trust between a
11 psychotherapist and a patient and that such trust
12 can only be established by an assurance of confiden-
13 tiality. This assurance serves the public interest by
14 facilitating the provision of appropriate treatment
15 for individuals.

16 (8) Section 264 of the Health Insurance Port-
17 ability and Accountability Act of 1996 (42 U.S.C.
18 1320d-2 note) establishes a deadline that Congress
19 enact legislation, before August 21, 1999, to protect
20 the privacy of protected health information.

21 **SEC. 3. PURPOSES.**

22 The purposes of this Act are as follows:

23 (1) To recognize that there is a right to privacy
24 with respect to health information, including genetic
25 information, and that this right must be protected.

1 (2) To create incentives to turn protected
2 health information into de-identified health informa-
3 tion, where appropriate.

4 (3) To designate an Office of Health Informa-
5 tion Privacy within the Department of Health and
6 Human Services to protect that right of privacy.

7 (4) To provide individuals with—

8 (A) access to health information of which
9 they are the subject; and

10 (B) the opportunity to challenge the accu-
11 racy and completeness of such information by
12 being able to file supplements to such informa-
13 tion.

14 (5) To provide individuals with the right to
15 limit the use and disclosure of protected health in-
16 formation.

17 (6) To establish strong and effective mecha-
18 nisms to protect against the unauthorized and inap-
19 propriate use of protected health information.

20 (7) To invoke the sweep of congressional pow-
21 ers, including the power to enforce the 14th amend-
22 ment, to regulate commerce, and to abrogate the im-
23 munity of the States under the 11th amendment, in
24 order to address violations of the rights of individ-
25 uals to privacy, to provide individuals with access to

1 their health information, and to prevent unauthor-
2 ized use of protected health information that is ge-
3 netic information.

4 (8) To establish strong and effective remedies
5 for violations of this Act.

6 (9) To protect the rights of States.

7 **SEC. 4. DEFINITIONS.**

8 In this Act:

9 (1) ADMINISTRATIVE BILLING INFORMATION.—

10 The term “administrative billing information”
11 means any of the following forms of protected health
12 information:

13 (A) Date of service, policy, patient identifi-
14 ers, and practitioner or facility identifiers.

15 (B) Diagnostic codes, in accordance with
16 medicare billing codes, for which treatment is
17 being rendered or requested.

18 (C) Complexity of service codes, indicating
19 duration of treatment.

20 (D) Total billed charges.

21 (2) AGENT.—The term “agent” means a person
22 who represents and acts for another person (a prin-
23 cipal) under a contract or relationship of agency, or
24 whose function is to bring about, modify, affect, ac-
25 cept performance of, or terminate, contractual obli-

gations between the principal and a third person.
With respect to an employer, the term includes the
employees of the employer.

(3) DE-IDENTIFIED HEALTH INFORMATION.—

(A) IN GENERAL.—The term “de-identified
health information” means any protected health
information, with respect to which—

(i) all personal identifiers, or other in-
formation that may be used by itself or in
combination with other information which
may be available to re-identify the subject
of the information, have been removed; and

(ii) a good faith effort to evaluate the
risks of re-identification of the subject of
such information in the context in which it
will be used or disclosed, has been made.

(B) EXAMPLES.—The term includes aggre-
gate statistics, redacted health information, in-
formation in which random or fictitious alter-
natives have been substituted for personally
identifiable information, and information in
which personally identifiable information has
been encrypted and the decryption key is main-
tained by a person otherwise authorized to have

1 access to such protected health information in
2 an identifiable format.

3 (4) DISCLOSE.—The term “disclose” means to
4 release, publish, share, transfer, transmit, dissemi-
5 nate, show, permit access to, re-identify, or other-
6 wise divulge protected health information to any per-
7 son other than the individual who is the subject of
8 such information. The term includes the initial dis-
9 closure and any subsequent redisclosure of protected
10 health information.

11 (5) DECRYPTION KEY.—The term “decryption
12 key” means the variable information used in or pro-
13 duced by a mathematical formula, code, or algo-
14 rithm, or any component thereof, used to encrypt or
15 decrypt wire or electronic communications or elec-
16 tronically stored information.

17 (6) EMPLOYER.—The term “employer” means
18 a person engaged in business affecting commerce
19 who has employees.

20 (7) ENCRYPTION.—The term “encryption”
21 means the scrambling of electronic or wire commu-
22 nications or electronically stored information using
23 mathematical formulas or algorithms sufficient to
24 preserve the confidentiality, integrity, and authentic-
25 ity of such communications or information.

1 (8) HEALTH CARE.—The term “health care”
2 means—

3 (A) preventive, diagnostic, therapeutic, re-
4 habilitative, maintenance, or palliative care, in-
5 cluding appropriate assistance with disease or
6 symptom management and maintenance, coun-
7 seling, service, or procedure—

8 (i) with respect to the physical or
9 mental condition of an individual; or

10 (ii) affecting the structure or function
11 of the human body or any part of the
12 human body, including the banking of
13 blood, sperm, organs, or any other tissue;
14 and

15 (B) any sale or dispensing of a drug, de-
16 vice, equipment, or other health care related
17 item to an individual, or for the use of an indi-
18 vidual, pursuant to a prescription.

19 (9) HEALTH CARE PROVIDER.—The term
20 “health care provider” means a person who, with re-
21 spect to a specific item of protected health informa-
22 tion, receives, creates, uses, maintains, or discloses
23 the information while acting in whole or in part in
24 the capacity of—

1 (A) a person who is licensed, certified, reg-
2 istered, or otherwise authorized by Federal or
3 State law to provide an item or service that
4 constitutes health care in the ordinary course of
5 business, or practice of a profession;

6 (B) a Federal or State program that di-
7 rectly provides items or services that constitute
8 health care to beneficiaries; or

9 (C) an officer or employee or agent of a
10 person described in subparagraph (A) or (B)
11 who is engaged in the provision of health care
12 or who uses health information.

13 (10) HEALTH OR LIFE INSURER.—The term
14 “health or life insurer” means a health insurance
15 issuer (as defined in section 9805(b)(2) of the Inter-
16 nal Revenue Code of 1986) or a life insurance com-
17 pany (as defined in section 816 of such Code) and
18 includes the employees and agents of such a person.

19 (11) HEALTH OVERSIGHT AGENCY.—The term
20 “health oversight agency”—

21 (A) means a person who—

22 (i) performs or oversees the perform-
23 ance of an assessment, investigation, or
24 prosecution relating to compliance with
25 legal or fiscal standards relating to health

1 care fraud or fraudulent claims regarding
2 health care, health services or equipment,
3 or related activities and items; and

4 (ii) is a public executive branch agen-
5 cy, acting on behalf of a public executive
6 branch agency, acting pursuant to a re-
7 quirement of a public executive branch
8 agency, or carrying out activities under a
9 Federal or State law governing an assess-
10 ment, evaluation, determination, investiga-
11 tion, or prosecution described in clause (i);
12 and

13 (B) includes the employees and agents of
14 such a person.

15 (12) HEALTH PLAN.—The term “health plan”
16 means any health insurance plan, including any hos-
17 pital or medical service plan, dental or other health
18 service plan or health maintenance organization
19 plan, or other program providing or arranging for
20 the provision of health benefits, whether or not fund-
21 ed through the purchase of insurance. The term in-
22 cludes employee welfare benefit plans and group
23 plans (as defined in sections 3 and 607 of the Em-
24 ployee Retirement Income Security Act of 1974 (29
25 U.S.C. 1002 and 1167)).

1 (13) HEALTH RESEARCHER.—The term “health
2 researcher” means a person who, with respect to a
3 specific item of protected health information, re-
4 ceives the information—

5 (A) pursuant to section 210 (relating to
6 health research); or

7 (B) while acting in whole or in part in the
8 capacity of an officer, employee, or agent of a
9 person who receives the information pursuant
10 to such section.

11 (14) LAW ENFORCEMENT INQUIRY.—The term
12 “law enforcement inquiry” means a lawful executive
13 branch investigation or official proceeding inquiring
14 into a violation of, or failure to comply with, any
15 criminal or civil statute or any regulation, rule, or
16 order issued pursuant to such a statute.

17 (15) OFFICE OF HEALTH INFORMATION PRI-
18 VACY.—The term “Office of Health Information Pri-
19 vacy” means the Office of Health Information Pri-
20 vacy designated under section 301.

21 (16) PERSON.—The term “person” means a
22 government, governmental subdivision of an execu-
23 tive branch agency or authority; corporation; com-
24 pany; association; firm; partnership; society; estate;

1 trust; joint venture; individual; individual represent-
2 ative; tribal government; and any other legal entity.

3 (17) PROTECTED HEALTH INFORMATION.—

4 (A) IN GENERAL.—The term “protected
5 health information” means any information, in-
6 cluding genetic information, demographic infor-
7 mation, and tissue samples collected from an
8 individual, whether oral or recorded in any form
9 or medium, that—

10 (i) is created or received by a health
11 care provider, health researcher, health
12 plan, health oversight agency, public health
13 authority, employer, health or life insurer,
14 school or university; and

15 (ii)(I) relates to the past, present, or
16 future physical or mental health or condi-
17 tion of an individual (including individual
18 cells and their components), the provision
19 of health care to an individual, or the past,
20 present, or future payment for the provi-
21 sion of health care to an individual; and

22 (II)(aa) identifies an individual; or

23 (bb) with respect to which there is a
24 reasonable basis to believe that the infor-

1 mation can be used to identify an individ-
2 ual; and

3 (B) DECRYPTION KEY.—The term “pro-
4 tected health information” includes any infor-
5 mation described in paragraph (5).

6 (18) PUBLIC HEALTH AUTHORITY.—The term
7 “public health authority” means an authority or in-
8 strumentality of the United States, a tribal govern-
9 ment, a State, or a political subdivision of a State
10 that is—

11 (A) primarily responsible for public health
12 matters; and

13 (B) primarily engaged in activities such as
14 injury reporting, public health surveillance, and
15 public health investigation or intervention.

16 (19) RE-IDENTIFY.—The term “re-identify”,
17 when used with respect to de-identified health infor-
18 mation, means an attempt, successful or otherwise,
19 to ascertain—

20 (A) the identity of the individual who is
21 the subject of such information; or

22 (B) the decryption key with respect to the
23 information (when undertaken with knowledge
24 that such key would allow for the identification

1 of the individual who is the subject of such in-
2 formation).

3 (20) SCHOOL OR UNIVERSITY.—The term
4 “school or university” means an institution or place
5 for instruction or education, including an elementary
6 school, secondary school, or institution of higher
7 learning, a college, or an assemblage of colleges
8 united under one corporate organization or govern-
9 ment.

10 (21) SECRETARY.—The term “Secretary”
11 means the Secretary of Health and Human Services.

12 (22) STATE.—The term “State” includes the
13 District of Columbia, Puerto Rico, the Virgin Is-
14 lands, Guam, American Samoa, and the Northern
15 Mariana Islands.

16 (23) TO THE MAXIMUM EXTENT PRAC-
17 TICABLE.—The term “to the maximum extent prac-
18 ticable” means the level of compliance that a reason-
19 able person would deem technologically feasible so
20 long as such feasibility is periodically evaluated in
21 light of scientific advances.

22 (24) WRITING.—The term “writing” means
23 writing in either a paper-based or computer-based
24 form, including electronic and digital signatures.

1 **TITLE I—INDIVIDUALS' RIGHTS**
2 **Subtitle A—Access to Protected**
3 **Health Information by Subjects**
4 **of the Information**

5 **SEC. 101. INSPECTION AND COPYING OF PROTECTED**
6 **HEALTH INFORMATION.**

7 (a) **RIGHT OF INDIVIDUAL.—**

8 (1) **IN GENERAL.**—A health care provider,
9 health plan, employer, health or life insurer, school,
10 or university, or a person acting as the agent of any
11 such person, shall permit an individual who is the
12 subject of protected health information, or the indi-
13 vidual's designee, to inspect and copy protected
14 health information concerning the individual, includ-
15 ing records created under sections 102, 112, 202,
16 203, 208, and 211, that such person maintains.

17 (2) **PROCEDURES AND FEES.**—A person de-
18 scribed in paragraph (1) may set forth appropriate
19 procedures to be followed for inspection and copying
20 under such paragraph and may require an individual
21 to pay fees associated with such inspection and copy-
22 ing in an amount that is not in excess of the actual
23 costs of providing such copying. Such fees may not
24 be assessed where such an assessment would have
25 the effect of inhibiting an individual from gaining

1 access to the information described in paragraph
2 (1).

3 (b) DEADLINE.—A person described in subsection
4 (a)(1) shall comply with a request for inspection or copy-
5 ing of protected health information under this section not
6 later than 15 business days after the date on which the
7 person receives the request.

8 (c) RULES GOVERNING AGENTS.—A person acting as
9 the agent of a person described in subsection (a) shall pro-
10 vide for the inspection and copying of protected health in-
11 formation if—

12 (1) the protected health information is retained
13 by the agent; and

14 (2) the agent has been asked by the person in-
15 volved to fulfill the requirements of this section.

16 (d) SPECIAL RULE RELATING TO ONGOING CLINICAL
17 TRIALS.—With respect to protected health information
18 that is created as part of an individual's participation in
19 an ongoing clinical trial, access to the information shall
20 be provided consistent with the individual's agreement to
21 participate in the clinical trial.

22 **SEC. 102. SUPPLEMENTS TO PROTECTED HEALTH INFOR-**
23 **MATION.**

24 (a) IN GENERAL.—Not later than 45 days after the
25 date on which a health care provider, health plan, em-

1 ployer, health or life insurer, school, or university, or a
2 person acting as the agent of any such person, receives
3 from an individual a request in writing to supplement pro-
4 tected health information concerning the individual, such
5 person—

6 (1) shall add the supplement requested to the
7 information;

8 (2) shall inform the individual that the supple-
9 ment has been made; and

10 (3) shall make reasonable efforts to inform any
11 person to whom the portion of the unsupplemented
12 information was previously disclosed, of any sub-
13 stantive supplement that has been made.

14 (b) REFUSAL TO SUPPLEMENT.—If a person de-
15 scribed in subsection (a) declines to make the supplement
16 requested under such subsection, the person shall inform
17 the individual in writing of—

18 (1) the reasons for declining to make the sup-
19 plement;

20 (2) any procedures for further review of the de-
21 clining of such supplement; and

22 (3) the individual's right to file with the person
23 a concise statement setting forth the requested sup-
24 plement and the individual's reasons for disagreeing
25 with the declining person and the individual's right

1 to include a copy of this refusal in his or her health
2 record.

3 (c) STATEMENT OF DISAGREEMENT.—If an individ-
4 ual has filed with a person a statement of disagreement
5 under subsection (b)(3), the person, in any subsequent dis-
6 closure of the disputed portion of the information—

7 (1) shall include, at the individual's request, a
8 copy of the individual's statement; and

9 (2) may include a concise statement of the rea-
10 sons for not making the requested supplement.

11 (d) RULES GOVERNING AGENTS.—A person acting as
12 the agent of a person described in subsection (a) shall not
13 be required to make a supplement to protected health in-
14 formation, except where—

15 (1) the protected health information is retained
16 by the agent; and

17 (2) the agent has been asked by such person to
18 fulfill the requirements of this section.

19 **SEC. 103. NOTICE OF PRIVACY PRACTICES.**

20 (a) PREPARATION OF WRITTEN NOTICE.—A health
21 care provider, health plan, health oversight agency, public
22 health authority, employer, health or life insurer, school,
23 or university, or a person acting as the agent of any such
24 person, shall prepare a written notice of the privacy prac-

1 tices of the person that provides information with respect
2 to the following:

3 (1) The procedures for an individual to author-
4 ize disclosures of protected health information, and
5 to object to, modify, and revoke such authorizations.

6 (2) The right of an individual to inspect, copy,
7 and supplement the protected health information.

8 (3) The right of an individual not to have em-
9 ployment or the receipt of services conditioned upon
10 the execution by the individual of an authorization
11 for disclosure.

12 (4) A description of the categories or types of
13 employees, by general category or by general job de-
14 scription, who have access to or use of protected
15 health information within the person.

16 (5) A simple, concise description of any infor-
17 mation systems used to store or transmit protected
18 health information, including a description of any
19 linkages made with other electronic systems or data-
20 bases outside the person.

21 (6) The right of the individual to request seg-
22 regation of protected health information, and to re-
23 strict the use of such information by employees,
24 agents, and contractors of a person.

1 (7) The circumstances under which the infor-
2 mation may be used or disclosed without an author-
3 ization executed by the individual.

4 (8) A statement that an individual may elect to
5 pay for health care from the individual's own funds
6 and information on the right of such an individual
7 to elect for identifying information not to be dis-
8 closed to anyone other than health care providers,
9 unless such disclosure is required by mandatory re-
10 porting requirements or other similar information
11 collection duties required by law.

12 (b) PROVISION AND POSTING OF WRITTEN NO-
13 TICE.—

14 (1) PROVISION.—A person described in sub-
15 section (a) shall provide a copy of the written notice
16 of privacy practices required under such
17 subsection—

18 (A) at the time an authorization is sought
19 for disclosure of protected health information;
20 and

21 (B) upon the request of an individual.

22 (2) POSTING.—A person described in subsection
23 (a) shall post, in a clear and conspicuous manner, a
24 brief summary of the privacy practices of the person.

1 (c) MODEL NOTICE.—The director of the Office of
2 Health Information Privacy, after notice and opportunity
3 for public comment, shall develop and disseminate model
4 notices of privacy practices, and model summary notices
5 for posting, for use under this section. Use of such a model
6 notice shall be deemed to satisfy the requirements of this
7 section.

8 **Subtitle B—Establishment of** 9 **Safeguards**

10 **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

11 (a) IN GENERAL.—A health care provider, health
12 plan, health oversight agency, public health authority, em-
13 ployer, health researcher, law enforcement official, health
14 or life insurer, school, or university, or a person acting
15 as the agent of any such person, shall establish and main-
16 tain appropriate administrative, organizational, technical,
17 and physical safeguards and procedures to ensure the con-
18 fidentiality, security, accuracy, and integrity of protected
19 health information created, received, obtained, main-
20 tained, used, transmitted, or disposed of by such person.

21 (b) FACTORS TO BE CONSIDERED.—The policies and
22 safeguards under subsection (a) shall ensure that—

23 (1) protected health information is used or dis-
24 closed only when necessary;

1 (2) the categories of personnel who will have ac-
2 cess to protected health information are identified;
3 and.

4 (3) the feasibility of limiting access to protected
5 health information is considered.

6 (c) **MODEL GUIDELINES.**—The Secretary, in con-
7 sultation with the Director of the Office of Health Infor-
8 mation Privacy appointed under section 301, after notice
9 and opportunity for public comment, shall develop and dis-
10 seminate model guidelines for the establishment of safe-
11 guards and procedures for use under this section, such
12 as, where appropriate, individual authentication of uses of
13 computer systems, access controls, audit trails, encryption,
14 physical security, protection of remote access points and
15 protection of external electronic communications, periodic
16 security assessments, incident reports, and sanctions. The
17 director shall update and disseminate the guidelines, as
18 appropriate, to take advantage of new technologies.

19 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

20 (a) **IN GENERAL.**—A health care provider, health
21 plan, health oversight agency, public health authority, em-
22 ployer, health researcher, law enforcement official, health
23 or life insurer, school, or university, or a person acting
24 as the agent of any such person, shall establish and main-
25 tain, with respect to any protected health information dis-

1 closure that is not related to payment or treatment, a
2 record of the disclosure in accordance with regulations
3 issued by the Secretary in consultation with the director
4 of the Office of Health Information Privacy.

5 (b) MAINTENANCE OF RECORD.—A record estab-
6 lished under subsection (a) shall be maintained for not less
7 than 7 years.

8 (c) ELECTRONIC RECORDS.—A health care provider,
9 health plan, health oversight agency, public health author-
10 ity, employer, health researcher, law enforcement official,
11 health or life insurer, school, or university, or a person
12 acting as the agent of any such person, shall, to the maxi-
13 mum extent practicable, maintain an accessible electronic
14 record concerning each access, or attempt to access,
15 whether authorized or unauthorized, successful or unsuc-
16 cessful, protected health information maintained by such
17 person in electronic form. The record shall include the
18 identity of the specific individual accessing or attempting
19 to gain such access (or a way to identify that individual
20 or information helpful in determining the identity of such
21 individual), information sufficient to identify the protected
22 health information sought or accessed, and other appro-
23 priate information.

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

SEC. 201. GENERAL RULES REGARDING USE AND DISCLOSURE.

(a) PROHIBITION.—

(1) **GENERAL RULE.**—A health care provider, health plan, health oversight agency, public health authority, employer, health researcher, law enforcement official, health or life insurer, school, or university may not disclose or use protected health information except as authorized under this Act.

(2) **RULE OF CONSTRUCTION.**—Disclosure of de-identified health information shall not be construed as a disclosure of protected health information.

(b) SCOPE OF DISCLOSURE.—

(1) **IN GENERAL.**—A disclosure of protected health information under this title shall be limited to the minimum amount of information necessary to accomplish the purpose for which the disclosure is made.

(2) **DETERMINATION.**—The determination as to what constitutes the minimum disclosure possible for purposes of paragraph (1) shall be made by a health care provider.

1 (c) USE OR DISCLOSURE FOR PURPOSE ONLY.—A
2 recipient of information pursuant to this title may use or
3 disclose such information solely to carry out the purpose
4 for which the information was disclosed.

5 (d) NO GENERAL REQUIREMENT TO DISCLOSE.—
6 Nothing in this title permitting the disclosure of protected
7 health information shall be construed to require such dis-
8 closure.

9 (e) IDENTIFICATION OF DISCLOSED INFORMATION AS
10 PROTECTED HEALTH INFORMATION.—Protected health
11 information disclosed pursuant to this title shall be clearly
12 identified as protected health information that is subject
13 to this Act.

14 (f) DISCLOSURE BY AGENTS.—An agent of a person
15 described in subsection (a)(1), who receives protected
16 health information from the person while acting within the
17 scope of the agency, shall be subject to this title to the
18 same extent as the person and for the duration of the pe-
19 riod in which the agent holds the information.

20 (g) CREATION OF DE-IDENTIFIED INFORMATION.—
21 Notwithstanding subsection (c), but subject to the other
22 provisions of this section, a person described in subsection
23 (a)(1) may disclose protected health information to an em-
24 ployee or other agent of the person for purposes of creat-
25 ing de-identified information.

1 (h) UNAUTHORIZED USE OR DISCLOSURE OF THE
2 DECRYPTION KEY.—The unauthorized disclosure of a
3 decryption key shall be deemed to be a disclosure of pro-
4 tected health information. The unauthorized use of a
5 decryption key or de-identified health information in order
6 to identify an individual is deemed to be disclosure of pro-
7 tected health information.

8 (i) NO WAIVER.—Except as provided in this Act, an
9 authorization to disclose personally identifiable health in-
10 formation executed by an individual pursuant to section
11 202 or 203 shall not be construed as a waiver of any rights
12 that the individual has under other Federal or State laws,
13 the rules of evidence, or common law.

14 (j) DEFINITIONS.—For purposes of this title:

15 (1) INVESTIGATIVE OR LAW ENFORCEMENT OF-
16 FICER.—The term “investigative or law enforcement
17 officer” means any officer of the United States or of
18 a State or political subdivision thereof, who is em-
19 powered by law to conduct investigations of, or to
20 make arrests for, criminal offenses, and any attor-
21 ney authorized by law to prosecute or participate in
22 the prosecution of such offenses.

23 (2) SEGREGATE.—The term “segregate” means
24 to place a designated subset of an individuals pro-
25 tected health information in a location or computer

1 file that is separate from the location or computer
2 file used to store protected health information and
3 where access to or use of any information so seg-
4 regated may be effectively limited to those persons
5 who are authorized by the individual to access or use
6 such information.

7 (3) SIGNED.—The term “signed” refers to both
8 signatures in ink and electronic signatures, and the
9 term “written” refers to both paper and computer-
10 ized formats.

11 **SEC. 202. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**
12 **TECTED HEALTH INFORMATION FOR TREAT-**
13 **MENT AND PAYMENT.**

14 (a) REQUIREMENTS RELATING TO EMPLOYERS,
15 HEALTH PLANS, HEALTH OR LIFE INSURERS, UNIN-
16 SURED INDIVIDUALS, AND PROVIDERS.—

17 (1) IN GENERAL.—To satisfy the requirement
18 under section 201(a)(1), an employer, health plan,
19 health or life insurer, or health care provider that
20 seeks to disclose protected health information in con-
21 nection with treatment or payment shall obtain an
22 authorization that satisfies the requirements of this
23 section. The authorization may be a single author-
24 ization.

1 (2) EMPLOYERS.—Every employer offering a
2 health plan to its employees shall, at the time of an
3 employee's enrollment in the health plan, obtain a
4 signed, written authorization that is a legal, in-
5 formed authorization that satisfies the requirements
6 of subsection (b) concerning the use and disclosure
7 of protected health information for treatment or
8 payment with respect to each individual who is eligi-
9 ble to receive care under the health plan.

10 (3) HEALTH PLANS, HEALTH OR LIFE INSUR-
11 ERS.—Every health plan or health or life insurer of-
12 fering enrollment to individual or nonemployer
13 groups shall, at the time of enrollment in the plan
14 or insurance, obtain a signed, written authorization
15 that is a legal, informed authorization that satisfies
16 the requirements of subsection (b) concerning the
17 use and disclosure of protected health information
18 with respect to each individual who is eligible to re-
19 ceive care under the plan or insurance.

20 (4) UNINSURED.—An originating provider pro-
21 viding health care in other than a network plan set-
22 ting, or providing health care to an uninsured indi-
23 vidual, shall obtain a signed, written authorization
24 that satisfies the requirements of subsection (b) to
25 use protected health information in providing health

1 care or arranging for health care from other provid-
2 ers or seeking payment for the provision of health
3 care services.

4 (5) PROVIDERS.—

5 (A) IN GENERAL.—Every health care pro-
6 vider providing health care to an individual who
7 has not given the appropriate authorization
8 under this section shall, at the time of provid-
9 ing such care, obtain a signed, written author-
10 ization that is a legal, informed authorization,
11 that satisfies the requirements of subsection
12 (b), concerning the use and disclosure of pro-
13 tected health information with respect to such
14 individual.

15 (B) RULE OF CONSTRUCTION.—Subpara-
16 graph (A) shall not be construed to preclude
17 the provision of health care to an individual
18 who has not given appropriate authorization
19 prior to receipt of such care if—

20 (i) the health care provider involved
21 determines that such care is essential; and

22 (ii) the individual can reasonably be
23 expected to sign an authorization for such
24 care when appropriate.

1 (b) REQUIREMENTS FOR INDIVIDUAL AUTHORIZA-
2 TION.—To satisfy the requirements of this subsection, an
3 authorization to disclose protected health information—

4 (1) shall identify, by general job description or
5 other functional description, persons authorized to
6 disclose the information;

7 (2) shall describe the nature of the information
8 to be disclosed;

9 (3) shall identify, by general job description or
10 other functional description, persons to whom the in-
11 formation is to be disclosed, including individuals
12 employed by, or operating within, an entity to which
13 information is authorized to be disclosed;

14 (4) shall describe the purpose of the disclosures;

15 (5) shall permit the executing individual to indi-
16 cate that a particular individual listed on the author-
17 ization is not authorized to receive protected health
18 information concerning the individual, except as pro-
19 vided for in subsection (c)(3);

20 (6) shall provide the means by which an individ-
21 ual may indicate that some of the individual's pro-
22 tected health information should be segregated and
23 to what persons such segregated information may be
24 disclosed;

1 (7) shall be subject to revocation by the individ-
2 ual and indicate that the authorization is valid until
3 revocation by the individual or until an event or date
4 specified; and

5 (8)(A) shall be—

6 (i) in writing, dated, and signed by the in-
7 dividual; or

8 (ii) in electronic form, dated and authenti-
9 cated by the individual using an authentication
10 method approved by the Secretary; and

11 (B) shall not have been revoked under subpara-
12 graph (A).

13 (c) LIMITATION ON AUTHORIZATIONS.—

14 (1) IN GENERAL.—Subject to paragraphs (2)
15 and (3), a person described in subsection (a) who
16 seeks an authorization under such subsection may
17 not condition the delivery of treatment or payment
18 for services on the receipt of such an authorization.

19 (2) RIGHT TO REQUIRE SELF PAYMENT.—If an
20 individual has refused to provide an authorization
21 for disclosure of administrative billing information to
22 a person and such authorization is necessary for a
23 health care provider to receive payment for services
24 delivered, the health care provider may require the

1 individual to pay from their own funds for the serv-
2 ices.

3 (3) RIGHT OF HEALTH CARE PROVIDER TO RE-
4 QUIRE AUTHORIZATION FOR TREATMENT PUR-
5 POSES.—If a health care provider that is seeking an
6 authorization for disclosure of an individual's pro-
7 tected health information believes that the disclosure
8 of such information is necessary so as not to endan-
9 ger the health or treatment of the individual, the
10 health care provider may condition the provision of
11 services upon the execution of the authorization by
12 the individual.

13 (d) MODEL AUTHORIZATIONS.—The Secretary, after
14 notice and opportunity for public comment, shall develop
15 and disseminate model written authorizations of the type
16 described in this section and model statements of the limi-
17 tations on authorizations. Any authorization obtained on
18 a model authorization form under section 202 developed
19 by the Secretary pursuant to the preceding sentence shall
20 be deemed to satisfy the requirements of this section.

21 (e) SEGREGATION OF FILES.—A person described in
22 subsection (a)(1) shall comply, to the maximum extent
23 practicable, with the request of an individual who is the
24 subject of protected health information—

1 (1) to segregate any type or amount of pro-
2 tected health information, other than administrative
3 billing information, held by the entity; and

4 (2) to limit the use or disclosure of the seg-
5 regated health information within the entity to those
6 persons specifically designated by the subject of the
7 protected health information.

8 (f) REVOCATION OF AUTHORIZATION.—

9 (1) IN GENERAL.—An individual may in writing
10 revoke or amend an authorization under this section
11 at any time, unless the disclosure that is the subject
12 of the authorization is required to effectuate pay-
13 ment for health care that has been provided to the
14 individual.

15 (2) HEALTH PLANS.—With respect to a health
16 plan, the authorization of an individual is deemed to
17 be revoked at the time of the cancellation or non-re-
18 newal of enrollment in the health plan, except as
19 may be necessary to complete plan administration
20 and payment requirements related to the individual's
21 period of enrollment.

22 (3) ACTIONS.—An individual may not maintain
23 an action against a person for disclosure of person-
24 ally identifiable health information—

1 (A) if the disclosure was made based on a
2 good faith reliance on the individual's author-
3 ization under this section at the time disclosure
4 was made;

5 (B) in a case in which the authorization is
6 revoked, if the disclosing person had no actual
7 or constructive notice of the revocation; or

8 (C) if the disclosure was for the purpose of
9 protecting another individual from imminent
10 physical harm, and is authorized under section
11 204.

12 (g) RECORD OF INDIVIDUAL'S AUTHORIZATIONS AND
13 REVOCATIONS.—Each person collecting or storing person-
14 ally identifiable health information shall maintain a record
15 for a period of 7 years of each authorization of an individ-
16 ual and any revocation thereof, and such record shall be-
17 come part of the personally identifiable health information
18 concerning such individual.

19 (h) RULE OF CONSTRUCTION.—Authorizations for
20 the disclosure of protected health information for treat-
21 ment or payment shall not authorize the disclosure of such
22 information by an individual with the intent to sell, trans-
23 fer, or use protected health information for commercial ad-
24 vantage other than the revenues directly derived from the
25 provision of health care to that individual. For such disclo-

1 sures, a separate authorization that satisfies the require-
2 ments of section 203 is required.

3 **SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**
4 **TECTED HEALTH INFORMATION OTHER THAN**
5 **FOR TREATMENT OR PAYMENT.**

6 (a) IN GENERAL.—To satisfy the requirement under
7 section 201(a)(1), a health care provider, health plan,
8 health oversight agency, public health authority, employer,
9 health researcher, law enforcement official, health or life
10 insurer, school, or university that seeks to disclose pro-
11 tected health information for a purpose other than treat-
12 ment or payment may obtain an authorization that satis-
13 fies the requirements of subsections (b) and (g) of section
14 202. Such an authorization under this section shall be sep-
15 arate from an authorization provided under section 202.

16 (b) LIMITATION ON AUTHORIZATIONS.—

17 (1) IN GENERAL.—A person subject to section
18 202 may not condition the delivery of treatment, or
19 payment for services, on the receipt of an authoriza-
20 tion described in this section.

21 (2) REQUIREMENT FOR SEPARATE AUTHORIZA-
22 TION.—A person subject to section 202 may not dis-
23 close protected health information to any employees
24 or agents who are responsible for making employ-
25 ment, work assignment, or other personnel decisions

1 with respect to the subject of the information with-
2 out a separate authorization permitting such a dis-
3 closure.

4 (c) MODEL AUTHORIZATIONS.—The Secretary, after
5 notice and opportunity for public comment, shall develop
6 and disseminate model written authorizations of the type
7 described in subsection (a). Any authorization obtained on
8 a model authorization form under this section developed
9 by the Secretary shall be deemed to meet the authorization
10 requirements of this section.

11 (d) REQUIREMENT TO RELEASE PROTECTED
12 HEALTH INFORMATION TO CORONERS AND MEDICAL EX-
13 AMINERS.—

14 (1) IN GENERAL.—When a Coroner or Medical
15 Examiner or their duly appointed deputies seek pro-
16 tected health information for the purpose of inquiry
17 into and determination of, the cause, manner, and
18 circumstances of an individual's death, the health
19 care provider, health plan, health oversight agency,
20 public health authority, employer, health researcher,
21 law enforcement officer, health or life insurer, school
22 or university involved shall provide that individual's
23 protected health information to the Coroner or Medi-
24 cal Examiner or to the duly appointed deputies with-
25 out undue delay.

1 (2) PRODUCTION OF ADDITIONAL INFORMA-
2 TION.—If a Coroner or Medical Examiner or their
3 duly appointed deputies receives health information
4 from an entity referred to in paragraph (1), such
5 health information shall remain as protected health
6 information unless the health information is at-
7 tached to or otherwise made a part of a Coroner's
8 or Medical Examiner's official report, in which case
9 it shall no longer be protected.

10 (3) EXEMPTION.—Health information attached
11 to or otherwise made a part of a Coroner's or Medi-
12 cal Examiner's official report, shall be exempt from
13 the provisions of this Act except as provided for in
14 this subsection.

15 (4) REIMBURSEMENT.—A Coroner or Medical
16 Examiner may require a person to reimburse their
17 Office for the reasonable costs associated with such
18 inspection or copying.

19 (e) REVOCATION OR AMENDMENT OF AUTHORIZA-
20 TION.—An individual may, in writing, revoke or amend an
21 authorization under this section at any time.

22 (f) ACTIONS.—An individual may not maintain an ac-
23 tion against a person for disclosure of protected health
24 information—

(1) if the disclosure was made based on a good faith reliance on the individual's authorization under this section at the time disclosure was made;

(2) in a case in which the authorization is revoked, if the disclosing person had no actual or constructive notice of the revocation; or

(3) if the disclosure was for the purpose of protecting another individual from imminent physical harm, and is authorized under section 204.

SEC. 204. EMERGENCY CIRCUMSTANCES.

(a) GENERAL RULE.—In the event of a threat of imminent physical or mental harm to the subject of protected health information, any person may, in order to allay or remedy such threat, disclose protected health information about such subject to a health care practitioner, health care facility, law enforcement authority, or emergency medical personnel.

(b) HARM TO OTHERS.—Any person may disclose protected health information about the subject of the information where—

(1) such subject has made an identifiable threat of serious injury or death with respect to an identifiable individual or group of individuals;

(2) the subject has the ability to carry out such threat; and

1 (3) the release of such information is necessary
2 to prevent or significantly reduce the possibility of
3 such threat being carried out.

4 **SEC. 205. PUBLIC HEALTH.**

5 (a) IN GENERAL.—A health care provider, health
6 plan, public health authority, employer, health or life in-
7 surer, law enforcement official, school, or university may
8 disclose protected health information to a public health au-
9 thority or other person authorized by public health law
10 when receipt of such information by the authority or other
11 person—

12 (1) relates directly to a specified public health
13 purpose;

14 (2) is reasonably likely to achieve such purpose;
15 and

16 (3) is intended for a purpose that cannot be
17 achieved through the receipt or use of de-identified
18 health information.

19 (b) PUBLIC HEALTH PURPOSE DEFINED.—For pur-
20 poses of subsection (a), the term “public health purpose”
21 means a population-based activity or individual effort, au-
22 thorized by law, aimed at the prevention of injury, disease,
23 or premature mortality, or the promotion of health, in a
24 community, including—

1 (1) assessing the health needs and status of the
2 community through public health surveillance and
3 epidemiological research;

4 (2) developing public health policy;

5 (3) responding to public health needs and emer-
6 gencies; and

7 (4) any other activities or efforts authorized by
8 law.

9 **SEC. 206. PROTECTION AND ADVOCACY AGENCIES.**

10 Any person who creates protected health information
11 or receives protected health information under this title
12 may disclose that information to a protection and advo-
13 cacy agency established under part C of title I of the De-
14 velopmental Disabilities Assistance and Bill of Rights Act
15 (42 U.S.C. 6041 et seq.) or under the Protection and Ad-
16 vocacy for Mentally Ill Individuals Act of 1986 (42 U.S.C.
17 10801 et seq.) when such agency can establish that there
18 is probable cause to believe that an individual who is the
19 subject of the protected health information is vulnerable
20 to abuse and neglect by an entity providing health or social
21 services to the individual.

22 **SEC. 207. OVERSIGHT.**

23 (a) IN GENERAL.—A health care provider, health
24 plan, employer, law enforcement official, health or life in-
25 surer, public health authority, health researcher, school or

1 university may disclose protected health information to a
2 health oversight agency to enable the agency to perform
3 a health oversight function authorized by law, if—

4 (1) the purpose for which the disclosure is to be
5 made cannot reasonably be accomplished without
6 protected health information;

7 (2) the purpose for which the disclosure is to be
8 made is of sufficient importance to warrant the ef-
9 fect on, or the risk to, the privacy of the individuals
10 that additional exposure of the information might
11 bring; and

12 (3) there is a reasonable probability that the
13 purpose of the disclosure will be accomplished.

14 (b) USE AND MAINTENANCE OF PROTECTED
15 HEALTH INFORMATION.—A health oversight agency that
16 receives protected health information under this section—

17 (1) shall rely upon a method to scramble or
18 otherwise safeguard, to the maximum extent prac-
19 ticable, the identity of the subject of the protected
20 health information in all work papers and all docu-
21 ments summarizing the health oversight activity;

22 (2) shall maintain in its records only such infor-
23 mation about an individual as is relevant and nec-
24 essary to accomplish the purpose for which the pro-
25 tected health information was obtained;

(3) shall maintain such information securely and limit access to such information to those persons with a legitimate need for access to carry out the purpose for which the records were obtained; and

(4) shall remove or destroy the information that allows subjects of protected health information to be identified at the earliest time at which removal or destruction can be accomplished, consistent with the purpose of the health oversight activity.

(c) USE OF PROTECTED HEALTH INFORMATION IN JUDICIAL PROCEEDINGS.—

(1) IN GENERAL.— The disclosure and use of protected health information in any judicial, administrative, court, or other public, proceeding or investigation relating to a health oversight activity shall be undertaken in such a manner as to preserve the confidentiality and privacy of individuals who are the subject of the information, unless disclosure is required by the nature of the proceedings.

(2) LIMITING DISCLOSURE.—Whenever disclosure of the identity of the subject of protected health information is required by the nature of the proceedings, or it is impracticable to redact the identity of such individual, the agency shall request that the

1 presiding judicial or administrative officer enter an
2 order limiting the disclosure of the identity of the
3 subject to the extent possible, including the redact-
4 ing of the protected health information from publicly
5 disclosed or filed pleadings or records.

6 (d) AUTHORIZATION BY A SUPERVISOR.—For pur-
7 poses of this section, the individual with authority to au-
8 thorize the oversight function involved shall provide to the
9 disclosing person described in subsection (a) a statement
10 that the protected health information is being sought for
11 a legally authorized oversight function.

12 (e) USE IN ACTION AGAINST INDIVIDUALS.—Pro-
13 tected health information about an individual that is dis-
14 closed under this section may not be used in, or disclosed
15 to any person for use in, an administrative, civil, or crimi-
16 nal action or investigation directed against the individual,
17 unless the action or investigation arises out of and is di-
18 rectly related to—

19 (1) the receipt of health care or payment for
20 health care;

21 (2) a fraudulent claim related to health; or

22 (3) oversight of a public health authority or a
23 health researcher.

1 **SEC. 208. DISCLOSURE FOR LAW ENFORCEMENT PUR-**
2 **POSES.**

3 (a) **LAW ENFORCEMENT ACCESS TO PROTECTED**
4 **HEALTH INFORMATION.**—A health care provider, health
5 researcher, health plan, health oversight agency, employer,
6 health or life insurer, school, university, a person acting
7 as the agent of any such person, or a person who receives
8 protected health information pursuant to section 204, may
9 disclose protected health information to an investigative
10 or law enforcement officer pursuant to a warrant issued
11 under the Federal Rules of Criminal Procedure, an equiva-
12 lent State warrant, a grand jury subpoena, or a court
13 order under limitations set forth in subsection (b).

14 (b) **REQUIREMENTS FOR COURT ORDERS FOR AC-**
15 **CESS TO PROTECTED HEALTH INFORMATION.**—A court
16 order for the disclosure of protected health information
17 under subsection (a) may be issued by any court that is
18 a court of competent jurisdiction and shall issue only if
19 the investigative or law enforcement officer submits a writ-
20 ten application upon oath or equivalent affirmation dem-
21 onstrating that there is probable cause to believe that—

22 (1) the protected health information sought is
23 relevant and material to an ongoing criminal inves-
24 tigation, except in the case of a State government
25 authority, such a court order shall not issue if pro-
26 hibited by the law of such State;

1 (2) the investigative or evidentiary needs of the
2 investigative or law enforcement officer cannot rea-
3 sonably be satisfied by de-identified health informa-
4 tion or by any other information; and

5 (3) the law enforcement need for the informa-
6 tion outweighs the privacy interest of the individual
7 to whom the information pertains.

8 (c) MOTIONS TO QUASH OR MODIFY.—A court
9 issuing an order pursuant to this section, on a motion
10 made promptly by the health care provider, health re-
11 searcher, health plan, health oversight agency, employer,
12 health or life insurer, school, university, a person acting
13 as the agent of any such person, or a person who receives
14 protected health information pursuant to section 204, may
15 quash or modify such order if the court finds that informa-
16 tion or records requested are unreasonably voluminous or
17 if compliance with such order otherwise would cause an
18 unreasonable burden on such persons.

19 (d) NOTICE.—

20 (1) IN GENERAL.—Except as provided in para-
21 graph (2), no order for the disclosure of protected
22 health information about an individual may be
23 issued by a court under this section unless prior no-
24 tice of the application for the order has been served
25 on the individual and the individual has been af-

1 forded an opportunity to oppose the issuance of the
2 order.

3 (2) NOTICE NOT REQUIRED.—An order for the
4 disclosure of protected health information about an
5 individual may be issued without prior notice to the
6 individual if the court finds that notice would be im-
7 practical because—

8 (A) the name and address of the individual
9 are unknown; or

10 (B) notice would risk destruction or un-
11 availability of the evidence.

12 (e) CONDITIONS.—Upon the granting of an order for
13 disclosure of protected health information under this sec-
14 tion, the court shall impose appropriate safeguards to en-
15 sure the confidentiality of such information and to protect
16 against unauthorized or improper use or disclosure.

17 (f) LIMITATION ON USE AND DISCLOSURE FOR
18 OTHER LAW ENFORCEMENT INQUIRIES.—Protected
19 health information about an individual that is disclosed
20 under this section may not be used in, or disclosed to any
21 person for use in, any administrative, civil, or criminal ac-
22 tion or investigation directed against the individual, unless
23 the action or investigation arises out of, or is directly re-
24 lated to, the law enforcement inquiry for which the infor-
25 mation was obtained.

1 (g) **DESTRUCTION OR RETURN OF INFORMATION.**—

2 When the matter or need for which protected health infor-
3 mation was disclosed to an investigative or law enforce-
4 ment officer or grand jury has concluded, including any
5 derivative matters arising from such matter or need, the
6 law enforcement agency or grand jury shall either destroy
7 the protected health information, or return it to the person
8 from whom it was obtained.

9 (h) **REDACTIONS.**—To the extent practicable, and
10 consistent with the requirements of due process, a law en-
11 forcement agency shall redact personally identifying infor-
12 mation from protected health information prior to the
13 public disclosure of such protected information in a judi-
14 cial or administrative proceeding.

15 (i) **EXCEPTION.**—This section shall not be construed
16 to limit or restrict the ability of law enforcement authori-
17 ties to gain information while in hot pursuit of a suspect
18 or if other exigent circumstances exist.

19 **SEC. 209. NEXT OF KIN AND DIRECTORY INFORMATION.**

20 (a) **NEXT OF KIN.**—A health care provider, or a per-
21 son who receives protected health information under sec-
22 tion 204, may disclose protected health information about
23 health care services provided to an individual to the indi-
24 vidual's next of kin, or to another person whom the indi-

1 vidual has identified, if at the time of the treatment of
2 the individual—

3 (1) the individual—

4 (A) has been notified of the individual's
5 right to object to such disclosure and the indi-
6 vidual has not objected to the disclosure; or

7 (B) is in a physical or mental condition
8 such that the individual is not capable of object-
9 ing, and there are no prior indications that the
10 individual would object; and

11 (2) the information disclosed relates to health
12 care services currently being provided to that indi-
13 vidual.

14 (b) DIRECTORY INFORMATION.—

15 (1) DISCLOSURE.—

16 (A) IN GENERAL.—Except as provided in
17 paragraph (2), with respect to an individual
18 who is admitted as an inpatient to a health care
19 facility, a person described in subsection (a)
20 may disclose information described in subpara-
21 graph (B) about the individual to any person if,
22 at the time of the admission, the individual—

23 (i) has been notified of the individ-
24 ual's right to object and has not objected
25 to the disclosure; or

1 (ii) is in a physical or mental condi-
2 tion such that the individual is not capable
3 of objecting and there are no prior indica-
4 tions that the individual would object.

5 (B) INFORMATION.—Information described
6 in this subparagraph is information that con-
7 sists only of 1 or more of the following items:

8 (i) The name of the individual who is
9 the subject of the information.

10 (ii) The general health status of the
11 individual, described as critical, poor, fair,
12 stable, or satisfactory or in terms denoting
13 similar conditions.

14 (iii) The location of the individual
15 within the health care facility to which the
16 individual is admitted.

17 (2) EXCEPTION.—Paragraph (1)(B)(iii) shall
18 not apply if disclosure of the location of the individ-
19 ual would reveal specific information about the phys-
20 ical or mental condition of the individual, unless the
21 individual expressly authorizes such disclosure.

22 (c) DIRECTORY OR NEXT-OF-KIN INFORMATION.—A
23 disclosure may not be made under this section if the dis-
24 closing person described in subsection (a) has reason to
25 believe that the disclosure of directory or next-of-kin infor-

1 mation could lead to the physical or mental harm of the
2 individual, unless the individual expressly authorizes such
3 disclosure.

4 **SEC. 210. HEALTH RESEARCH.**

5 (a) REGULATIONS.—

6 (1) IN GENERAL.—The requirements and pro-
7 tections provided for under part 46 of title 45, Code
8 of Federal Regulations (as in effect on the date of
9 enactment of this Act), shall apply to all health re-
10 search.

11 (2) EFFECTIVE DATE.—Paragraph (1) shall not
12 take effect until the Secretary has promulgated final
13 regulations to implement such paragraph.

14 (b) EVALUATION.—Not later than 24 months after
15 the date of enactment of this Act, the Secretary shall pre-
16 pare and submit to Congress detailed recommendations on
17 whether written informed consent should be required, and
18 if so, under what circumstances, before protected health
19 information can be used for health research.

20 (c) RECOMMENDATIONS.—The recommendations re-
21 quired to be submitted under subsection (b) shall
22 include—

23 (1) a detailed explanation of current institu-
24 tional review board practices, including the extent to
25 which the privacy of individuals is taken into ac-

1 count as a factor before allowing waivers and under
2 what circumstances informed consent is being
3 waived;

4 (2) a summary of how technology could be used
5 to strip identifying data for the purposes of re-
6 search;

7 (3) an analysis of the risks and benefits of re-
8 quiring informed consent versus the waiver of in-
9 formed consent;

10 (4) an analysis of the risks and benefits of
11 using protected health information for research pur-
12 poses other than the health research project for
13 which such information was obtained; and

14 (5) an analysis of the risks and benefits of al-
15 lowing individuals to consent or to use consent, at
16 the time of receiving medical treatment, to the pos-
17 sible future use of records of medical treatments for
18 research studies.

19 (d) CONSULTATION.—In carrying out this section,
20 the Secretary shall consult with individuals who have dis-
21 tinguished themselves in the fields of health research, pri-
22 vacy, related technology, consumer interests in health in-
23 formation, health data standards, and the provision of
24 health services.

1 (e) CONGRESSIONAL NOTICE.—Not later than 6
2 months after the date on which the Secretary submits to
3 Congress the recommendations required under subsection
4 (b), the Secretary shall propose to implement such rec-
5 ommendations through regulations promulgated on the
6 record after opportunity for a hearing, and shall advise
7 the Congress of such proposal.

8 (f) OTHER REQUIREMENTS.—

9 (1) OBLIGATIONS OF THE RECIPIENT.—A per-
10 son who receives protected health information pursu-
11 ant to this section shall remove or destroy, at the
12 earliest opportunity consistent with the purposes of
13 the project involved, information that would enable
14 an individual to be identified, unless—

15 (A) an institutional review board has de-
16 termined that there is a health or research jus-
17 tification for the retention of such identifiers;
18 and

19 (B) there is an adequate plan to protect
20 the identifiers from disclosure consistent with
21 this section; and

22 (2) PERIODIC REVIEW AND TECHNICAL ASSIST-
23 ANCE.—

24 (A) INSTITUTIONAL REVIEW BOARD.—Any
25 institutional review board that authorizes re-

1 search under this section shall provide the Sec-
2 retary with the names and addresses of the in-
3 stitutional review board members.

4 (B) TECHNICAL ASSISTANCE.—The Sec-
5 retary may provide technical assistance to insti-
6 tutional review boards described in this sub-
7 section.

8 (C) MONITORING.—The Secretary shall pe-
9 riodically monitor institutional review boards
10 described in this subsection.

11 (D) REPORTS.—Not later than 3 years
12 after the date of enactment of this Act, the Sec-
13 retary shall report to Congress regarding the
14 activities of institutional review boards de-
15 scribed in this subsection.

16 (g) LIMITATION.—Nothing in this section shall be
17 construed to permit protected health information that is
18 received by a researcher under this section to be accessed
19 for purposes other than research or as authorized by the
20 individual.

21 **SEC. 211. JUDICIAL AND ADMINISTRATIVE PURPOSES.**

22 (a) IN GENERAL.—A health care provider, health
23 plan, health oversight agency, employer, insurer, health or
24 life insurer, school or university, a person acting as the
25 agent of any such person, or a person who receives pro-

1 tected health information under section 204, may disclose
2 protected health information—

3 (1) pursuant to the standards and procedures
4 established in the Federal Rules of Civil Procedure
5 or comparable rules of other courts or administrative
6 agencies, in connection with litigation or proceedings
7 to which an individual who is the subject of the in-
8 formation is a party and in which the individual has
9 placed his or her physical or mental condition at
10 issue;

11 (2) to a court, and to others ordered by the
12 court, if in response to a court order issued by a
13 court of competent jurisdiction in accordance with
14 subsections (b) and (c); or

15 (3) if necessary to present to a court an appli-
16 cation regarding the provision of treatment of an in-
17 dividual or the appointment of a guardian.

18 (b) COURT ORDERS FOR ACCESS TO PROTECTED
19 HEALTH INFORMATION.—A court order for the disclosure
20 of protected health information under subsection (a) may
21 be issued only if the person seeking disclosure submits a
22 written application upon oath or equivalent affirmation
23 demonstrating by clear and convincing evidence that—

1 (1) the protected health information sought is
2 necessary for the adjudication of a material fact in
3 dispute in a civil proceeding;

4 (2) the adjudicative need cannot be reasonably
5 satisfied by de-identified health information or by
6 any other information; and

7 (3) the need for the information outweighs the
8 privacy interest of the individual to whom the infor-
9 mation pertains.

10 (c) NOTICE.—

11 (1) IN GENERAL.—Except as provided in para-
12 graph (2), no order for the disclosure of protected
13 health information about an individual may be
14 issued by a court unless notice of the application for
15 the order has been served on the individual and the
16 individual has been afforded an opportunity to op-
17 pose the issuance of the order.

18 (2) NOTICE NOT REQUIRED.—An order for the
19 disclosure of protected health information about an
20 individual may be issued without notice to the indi-
21 vidual if the court finds, by clear and convincing evi-
22 dence, that notice would be impractical because—

23 (A) the name and address of the individual
24 are unknown; or

1 (B) notice would risk destruction or un-
2 availability of the evidence.

3 (d) OBLIGATIONS OF RECIPIENT.—A person seeking
4 protected health information pursuant to subsection
5 (a)(1)—

6 (1) shall notify the individual or the individual's
7 attorney of the request for the information;

8 (2) shall provide the health care provider,
9 health plan, health oversight agency, employer, in-
10 surer, health or life insurer, school or university,
11 agent, or other person involved with a signed docu-
12 ment attesting—

13 (A) that the individual has placed his or
14 her physical or mental condition at issue in liti-
15 gation or proceedings in which the individual is
16 a party; and

17 (B) the date on which the individual or the
18 individual's attorney was notified under para-
19 graph (1); and

20 (3) shall not accept any requested protected
21 health information from the health care provider,
22 health plan, health oversight agency, employer, in-
23 surer, health or life insurer, school or university,
24 agent, or person until the termination of the 10-day

1 period beginning on the date notice was given under
2 paragraph (1).

3 **SEC. 212. INDIVIDUAL REPRESENTATIVES.**

4 (a) IN GENERAL.—Except as provided in subsections
5 (b) and (c), a person who is authorized by law (based on
6 grounds other than an individual's status as a minor), or
7 by an instrument recognized under law, to act as an agent,
8 attorney, proxy, or other legal representative of a individ-
9 ual, may, to the extent so authorized, exercise and dis-
10 charge the rights of the individual under this Act.

11 (b) HEALTH CARE POWER OF ATTORNEY.—A person
12 who is authorized by law (based on grounds other than
13 being a minor), or by an instrument recognized under law,
14 to make decisions about the provision of health care to
15 an individual who is incapacitated, may exercise and dis-
16 charge the rights of the individual under this Act to the
17 extent necessary to effectuate the terms or purposes of
18 the grant of authority.

19 (c) NO COURT DECLARATION.—If a physician or
20 other health care provider determines that an individual,
21 who has not been declared to be legally incompetent, suf-
22 fers from a medical condition that prevents the individual
23 from acting knowingly or effectively on the individual's
24 own behalf, the right of the individual to authorize disclo-

1 sure under this Act may be exercised and discharged in
2 the best interest of the individual by—

3 (1) a person described in subsection (b) with re-
4 spect to the individual;

5 (2) a person described in subsection (a) with re-
6 spect to the individual, but only if a person de-
7 scribed in paragraph (1) cannot be contacted after
8 a reasonable effort;

9 (3) the next of kin of the individual, but only
10 if a person described in paragraph (1) or (2) cannot
11 be contacted after a reasonable effort; or

12 (4) the health care provider, but only if a per-
13 son described in paragraph (1), (2), or (3) cannot be
14 contacted after a reasonable effort.

15 (d) RIGHTS OF MINORS.—

16 (1) INDIVIDUALS WHO ARE 18 OR LEGALLY CA-
17 PABLE.—In the case of an individual—

18 (A) who is 18 years of age or older, all
19 rights of the individual under this Act shall be
20 exercised by the individual; or

21 (B) who, acting alone, can obtain a type of
22 health care without violating any applicable law,
23 and who has sought such care, the individual
24 shall exercise all rights of an individual under

1 this Act with respect to protected health infor-
2 mation relating to such health care.

3 (2) INDIVIDUALS UNDER 18.—Except as pro-
4 vided in paragraph (1)(B), in the case of an individ-
5 ual who is—

6 (A) under 14 years of age, all of the indi-
7 vidual's rights under this Act shall be exercised
8 through the parent or legal guardian; or

9 (B) 14 through 17 years of age, the rights
10 of inspection and supplementation, and the
11 right to authorize use and disclosure of pro-
12 tected health information of the individual shall
13 be exercised by the individual, or by the parent
14 or legal guardian of the individual.

15 (e) DECEASED INDIVIDUALS.—

16 (1) APPLICATION OF ACT.—The provisions of
17 this Act shall continue to apply to protected health
18 information concerning a deceased individual.

19 (2) EXERCISE OF RIGHTS ON BEHALF OF A DE-
20 CEASED INDIVIDUAL.—A person who is authorized
21 by law or by an instrument recognized under law, to
22 act as an executor of the estate of a deceased indi-
23 vidual, or otherwise to exercise the rights of the de-
24 ceased individual, may, to the extent so authorized,
25 exercise and discharge the rights of such deceased

1 individual under this Act. If no such designee has
2 been authorized, the rights of the deceased individ-
3 ual may be exercised as provided for in subsection
4 (c).

5 (3) IDENTIFICATION OF DECEASED INDIVID-
6 UAL.—A person described in section 209(a) may dis-
7 close protected health information if such disclosure
8 is necessary to assist in the identification of a de-
9 ceased individual.

10 **SEC. 213. PROHIBITION AGAINST RETALIATION.**

11 A health care provider, health researcher, health
12 plan, health oversight agency, employer, health or life in-
13 surer, school or university, person acting as an agent of
14 any such person, or person who receives protected health
15 information under section 204 may not adversely affect
16 another person, directly or indirectly, because such person
17 has exercised a right under this Act, disclosed information
18 relating to a possible violation of this Act, or associated
19 with, or assisted, a person in the exercise of a right under
20 this Act.

1 **TITLE III—OFFICE OF HEALTH**
2 **INFORMATION PRIVACY OF**
3 **THE DEPARTMENT OF**
4 **HEALTH AND HUMAN SERV-**
5 **ICES**

6 **Subtitle A—Designation**

7 **SEC. 301. DESIGNATION.**

8 (a) IN GENERAL.—The Secretary shall designate an
9 office within the Department of Health and Human Serv-
10 ices to be known as the Office of Health Information Pri-
11 vacy. The Office shall be headed by a Director, who shall
12 be appointed by the Secretary.

13 (b) DUTIES.—The Director of the Office of Health
14 Information Privacy shall—

15 (1) receive and investigate complaints of alleged
16 violations of this Act;

17 (2) provide for the conduct of audits where ap-
18 propriate;

19 (3) provide guidance to the Secretary in the im-
20 plementation of this Act;

21 (4) prepare and submit the report described in
22 subsection (c);

23 (5) consult with, and provide recommendation
24 to, the Secretary concerning improvements in the

privacy and security of protected health information
and concerning medical privacy research needs; and

(6) carry out any other activities determined
appropriate by the Secretary.

(c) REPORT ON COMPLIANCE.—Not later than January 1 of the first calendar year beginning more than 1 year after the establishment of the Office under subsection (a), and every January 1 thereafter, the Director of the Office of Health Information Privacy shall prepare and submit to Congress a report concerning the number of complaints of alleged violations of this Act that are received during the year for which the report is being prepared. Such report shall describe the complaints and any remedial action taken concerning such complaints.

Subtitle B—Enforcement

CHAPTER 1—CRIMINAL PROVISIONS

SEC. 311. WRONGFUL DISCLOSURE OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—Part I of title 18, United States Code, is amended by adding at the end the following:

“CHAPTER 124—WRONGFUL DISCLOSURE OF PROTECTED HEALTH INFORMATION

“Sec.

“2801. Wrongful disclosure of protected health information.

1 **“§ 2801. Wrongful disclosure of protected health in-**
2 **formation**

3 “(a) OFFENSE.—The penalties described in sub-
4 section (b) shall apply to a person that knowingly and
5 intentionally—

6 “(1) obtains or attempts to obtain protected
7 health information relating to an individual in viola-
8 tion of title II of the Medical Information Privacy
9 and Security Act; or

10 “(2) discloses or attempts to disclose protected
11 health information to another person in violation of
12 title II of the Medical Information Privacy and Se-
13 curity Act.

14 “(b) PENALTIES.—A person described in subsection
15 (a) shall—

16 “(1) be fined not more than \$50,000, impris-
17 oned not more than 1 year, or both;

18 “(2) if the offense is committed under false pre-
19 tenses, be fined not more than \$250,000, imprisoned
20 not more than 5 years, or any combination of such
21 penalties; or

22 “(3) if the offense is committed with the intent
23 to sell, transfer, or use protected health information
24 for commercial advantage, personal gain, or mali-
25 cious harm, be fined not more than \$500,000, im-
26 prisoned not more than 10 years, excluded from par-

1 ticipation in any Federally funded health care pro-
2 grams, or any combination of such penalties.

3 “(c) SUBSEQUENT OFFENSES.—In the case of a per-
4 son described in subsection (a), the maximum penalties
5 described in subsection (b) shall be doubled for every sub-
6 sequent conviction for an offense arising out of a violation
7 or violations related to a set of circumstances that are dif-
8 ferent from those involved in the previous violation or set
9 of related violations described in such subsection (a).”.

10 (b) CLERICAL AMENDMENT.—The table of chapters
11 for part I of title 18, United States Code, is amended by
12 inserting after the item relating to chapter 123 the follow-
13 ing new item:

“124. Wrongful disclosure of protected health information 2801”.

14 **SEC. 312. DEBARMENT FOR CRIMES.**

15 (a) PURPOSE.—The purpose of this section is to pro-
16 mote the prevention and deterrence of instances of inten-
17 tional criminal actions which violate criminal laws which
18 are designed to protect the privacy of protected health in-
19 formation in a manner consistent with this Act.

20 (b) DEBARMENT.—Not later than 270 days after the
21 date of enactment of this Act, the Attorney General, in
22 consultation with the Secretary, shall promulgate regula-
23 tions and establish procedures to permit the debarment
24 of health care providers, health researchers, health or life
25 insurers, employers, or schools or universities from receiv-

1 ing benefits under any Federal health programs or other
2 Federal procurement program if the managers or officers
3 of such persons are found guilty of violating section 2801
4 of title 18, United States Code, have civil penalties im-
5 posed against such officers or managers under section 321
6 in connection with the illegal disclosure of protected health
7 information, or are found guilty of making a false state-
8 ment or obstructing justice related to attempting to con-
9 ceal or concealing such illegal disclosure. Such regulations
10 shall take into account the need for continuity of medical
11 care and may provide for a delay of any debarment im-
12 posed under this section to take into account the medical
13 needs of patients.

14 (c) CONSULTATION.—Before publishing a proposed
15 rule to implement subsection (b), the Attorney General
16 shall consult with State law enforcement officials, health
17 care providers, patient privacy rights' advocates, and other
18 appropriate persons, to gain additional information re-
19 garding the debarment of entities under subsection (b)
20 and the best methods to ensure the continuity of medical
21 care.

22 (d) REPORT.—The Attorney General shall annually
23 prepare and submit to the Committee on the Judiciary of
24 the House of Representatives and the Committee on the
25 Judiciary of the Senate a report concerning the activities

1 and debarment actions taken by the Attorney General
2 under this section.

3 (e) ASSISTANCE TO PREVENT CRIMINAL VIOLA-
4 TIONS.—The Attorney General, in cooperation with any
5 other appropriate individual, organization, or agency, may
6 provide advice, training, technical assistance, and guid-
7 ance regarding ways to reduce the incidence of improper
8 disclosure of protected health information.

9 (f) RELATIONSHIP TO OTHER AUTHORITIES.—A de-
10 barment imposed under this section shall not reduce or
11 diminish the authority of a Federal, State, or local govern-
12 mental agency or court to penalize, imprison, fine, sus-
13 pend, debar, or take other adverse action against a person,
14 in a civil, criminal, or administrative proceeding.

15 CHAPTER 2—CIVIL SANCTIONS

16 SEC. 321. CIVIL PENALTY.

17 (a) VIOLATION.—A health care provider, health re-
18 searcher, health plan, health oversight agency, public
19 health agency, law enforcement agency, employer, health
20 or life insurer, school, or university, or a person acting
21 as the agent of any such person, who the Secretary, in
22 consultation with the Attorney General, determines has
23 substantially and materially failed to comply with this Act
24 shall be subject, in addition to any other penalties that
25 may be prescribed by law—

1 (1) in a case in which the violation relates to
2 title I, to a civil penalty of not more than \$500 for
3 each such violation, but not to exceed \$5000 in the
4 aggregate for multiple violations;

5 (2) in a case in which the violation relates to
6 title II, to a civil penalty of not more than \$10,000
7 for each such violation, but not to exceed \$50,000
8 in the aggregate for multiple violations; or

9 (3) in a case in which the Secretary finds that
10 such violations have occurred with such frequency as
11 to constitute a general business practice, to a civil
12 penalty of not more than \$100,000.

13 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—
14 Section 1128A of the Social Security Act (42 U.S.C.
15 1320a-7a), other than subsections (a) and (b) and the
16 second sentence of subsection (f) of that section, shall
17 apply to the imposition of a civil, monetary, or exclusion-
18 ary penalty under this section in the same manner as such
19 provisions apply with respect to the imposition of a penalty
20 under section 1128A of such Act.

21 **SEC. 322. PROCEDURES FOR IMPOSITION OF PENALTIES.**

22 (a) INITIATION OF PROCEEDINGS.—

23 (1) IN GENERAL.—The Secretary, in consulta-
24 tion with the Attorney General, may initiate a pro-
25 ceeding to determine whether to impose a civil

1 money penalty under section 321. The Secretary
2 may not initiate an action under this section with re-
3 spect to any violation described in section 321 after
4 the expiration of the 6-year period beginning on the
5 date on which such violation was alleged to have oc-
6 curred. The Secretary may initiate an action under
7 this section by serving notice of the action in any
8 manner authorized by Rule 4 of the Federal Rules
9 of Civil Procedure.

10 (2) NOTICE AND OPPORTUNITY FOR HEAR-
11 ING.—The Secretary shall not make a determination
12 adverse to any person under paragraph (1) until the
13 person has been given written notice and an oppor-
14 tunity for the determination to be made on the
15 record after a hearing at which the person is entitled
16 to be represented by counsel, to present witnesses,
17 and to cross-examine witnesses against the person.

18 (3) ESTOPPEL.—In a proceeding under para-
19 graph (1) that—

20 (A) is against a person who has been con-
21 victed (whether upon a verdict after trial or
22 upon a plea of guilty or nolo contendere) of a
23 crime under section 2801 of title 18, United
24 States Code; and

1 (B) involves the same conduct as in the
2 criminal action;
3 the person is estopped from denying the essential
4 elements of the criminal offense.

5 (4) SANCTIONS FOR FAILURE TO COMPLY.—
6 The official conducting a hearing under this section
7 may sanction a person, including any party or attor-
8 ney, for failing to comply with an order or proce-
9 dure, failing to defend an action, or other mis-
10 conduct as would interfere with the speedy, orderly,
11 or fair conduct of the hearing. Such sanction shall
12 reasonably relate to the severity and nature of the
13 failure or misconduct. Such sanction may include—

14 (A) in the case of refusal to provide or per-
15 mit discovery, drawing negative factual infer-
16 ences or treating such refusal as an admission
17 by deeming the matter, or certain facts, to be
18 established;

19 (B) prohibiting a party from introducing
20 certain evidence or otherwise supporting a par-
21 ticular claim or defense;

22 (C) striking pleadings, in whole or in part;

23 (D) staying the proceedings;

24 (E) dismissal of the action;

25 (F) entering a default judgment;

1 (G) ordering the party or attorney to pay
2 attorneys' fees and other costs caused by the
3 failure or misconduct; and

4 (H) refusing to consider any motion or
5 other action which is not filed in a timely man-
6 ner.

7 (b) SCOPE OF PENALTY.—In determining the
8 amount or scope of any penalty imposed pursuant to sec-
9 tion 321, the Secretary shall take into account—

10 (1) the nature of claims and the circumstances
11 under which they were presented;

12 (2) the degree of culpability, history of prior of-
13 fenses, and financial condition of the person against
14 whom the claim is brought; and

15 (3) such other matters as justice may require.

16 (c) REVIEW OF DETERMINATION.—

17 (1) IN GENERAL.—Any person adversely af-
18 fected by a determination of the Secretary under
19 this section may obtain a review of such determina-
20 tion in the United States Court of Appeals for the
21 circuit in which the person resides, or in which the
22 claim was presented, by filing in such court (within
23 60 days following the date the person is notified of
24 the determination of the Secretary a written petition

1 requesting that the determination be modified or set
2 aside.

3 (2) FILING OF RECORD.—A copy of the petition
4 filed under paragraph (1) shall be forthwith trans-
5 mitted by the clerk of the court to the Secretary,
6 and thereupon the Secretary shall file in the Court
7 the record in the proceeding as provided in section
8 2112 of title 28, United States Code. Upon such fil-
9 ing, the court shall have jurisdiction of the proceed-
10 ing and of the question determined therein, and
11 shall have the power to make and enter upon the
12 pleadings, testimony, and proceedings set forth in
13 such record a decree affirming, modifying, remand-
14 ing for further consideration, or setting aside, in
15 whole or in part, the determination of the Secretary
16 and enforcing the same to the extent that such order
17 is affirmed or modified.

18 (3) CONSIDERATION OF OBJECTIONS.—No ob-
19 jection that has not been raised before the Secretary
20 with respect to a determination described in para-
21 graph (1) shall be considered by the court, unless
22 the failure or neglect to raise such objection shall be
23 excused because of extraordinary circumstances.

24 (4) FINDINGS.—The findings of the Secretary
25 with respect to questions of fact in an action under

1 this subsection, if supported by substantial evidence
2 on the record considered as a whole, shall be conclu-
3 sive. If any party shall apply to the court for leave
4 to adduce additional evidence and shall show to the
5 satisfaction of the court that such additional evi-
6 dence is material and that there were reasonable
7 grounds for the failure to adduce such evidence in
8 the hearing before the Secretary, the court may
9 order such additional evidence to be taken before the
10 Secretary and to be made a part of the record. The
11 Secretary may modify findings as to the facts, or
12 make new findings, by reason of additional evidence
13 so taken and filed, and shall file with the court such
14 modified or new findings, and such findings with re-
15 spect to questions of fact, if supported by substan-
16 tial evidence on the record considered as a whole,
17 and the recommendations of the Secretary, if any,
18 for the modification or setting aside of the original
19 order, shall be conclusive.

20 (5) EXCLUSIVE JURISDICTION.—Upon the filing
21 of the record with the court under paragraph (2),
22 the jurisdiction of the court shall be exclusive and its
23 judgment and decree shall be final, except that the
24 same shall be subject to review by the Supreme

1 Court of the United States, as provided for in sec-
2 tion 1254 of title 28, United States Code.

3 (d) RECOVERY OF PENALTIES.—

4 (1) IN GENERAL.—Civil money penalties im-
5 posed under this chapter may be compromised by
6 the Secretary and may be recovered in a civil action
7 in the name of the United States brought in United
8 States district court for the district where the claim
9 was presented, or where the claimant resides, as de-
10 termined by the Secretary. Amounts recovered under
11 this section shall be paid to the Secretary and depos-
12 ited as miscellaneous receipts of the Treasury of the
13 United States.

14 (2) DEDUCTION FROM AMOUNTS OWING.—The
15 amount of any penalty, when finally determined
16 under this section, or the amount agreed upon in
17 compromise under paragraph (1), may be deducted
18 from any sum then or later owing by the United
19 States or a State to the person against whom the
20 penalty has been assessed.

21 (e) DETERMINATION FINAL.—A determination by
22 the Secretary to impose a penalty under section 321 shall
23 be final upon the expiration of the 60-day period referred
24 to in subsection (c)(1). Matters that were raised or that
25 could have been raised in a hearing before the Secretary

1 or in an appeal pursuant to subsection (c) may not be
2 raised as a defense to a civil action by the United States
3 to collect a penalty under section 321.

4 (f) SUBPOENA AUTHORITY.—

5 (1) IN GENERAL.—For the purpose of any
6 hearing, investigation, or other proceeding author-
7 ized or directed under this section, or relative to any
8 other matter within the jurisdiction of the Secretary
9 hereunder, the Secretary shall have the power to
10 issue subpoenas requiring the attendance and testi-
11 mony of witnesses and the production of any evi-
12 dence that relates to any matter under investigation
13 or in question. Such attendance of witnesses and
14 production of evidence at the designated place of
15 such hearing, investigation, or other proceeding may
16 be required from any place in the United States or
17 in any Territory or possession thereof.

18 (2) SERVICE.—Subpoenas of the Secretary
19 under paragraph (1) shall be served by anyone au-
20 thorized by the Secretary by delivering a copy there-
21 of to the individual named therein.

22 (3) PROOF OF SERVICE.—A verified return by
23 the individual serving the subpoena under this sub-
24 section setting forth the manner of service shall be
25 proof of service.

1 (4) FEES.—Witnesses subpoenaed under this
2 subsection shall be paid the same fees and mileage
3 as are paid witnesses in the district court of the
4 United States.

5 (5) REFUSAL TO OBEY.—In case of contumacy
6 by, or refusal to obey a subpoena duly served upon,
7 any person, any district court of the United States
8 for the judicial district in which such person charged
9 with contumacy or refusal to obey is found or re-
10 sides or transacts business, upon application by the
11 Secretary, shall have jurisdiction to issue an order
12 requiring such person to appear and give testimony,
13 or to appear and produce evidence, or both. Any fail-
14 ure to obey such order of the court may be punished
15 by the court as contempt thereof.

16 (g) INJUNCTIVE RELIEF.—Whenever the Secretary
17 has reason to believe that any person has engaged, is en-
18 gaging, or is about to engage in any activity which makes
19 the person subject to a civil monetary penalty under sec-
20 tion 321, the Secretary may bring an action in an appro-
21 priate district court of the United States (or, if applicable,
22 a United States court of any territory) to enjoin such ac-
23 tivity, or to enjoin the person from concealing, removing,
24 encumbering, or disposing of assets which may be required

1 in order to pay a civil monetary penalty if any such pen-
2 alty were to be imposed or to seek other appropriate relief.

3 (h) AGENCY.—A principal is jointly and severally lia-
4 ble with the principal's agent for penalties under section
5 321 for the actions of the principal's agent acting within
6 the scope of the agency.

7 **SEC. 323. CIVIL ACTION BY INDIVIDUALS.**

8 (a) IN GENERAL.—Any individual whose rights under
9 this Act have been knowingly or negligently violated may
10 bring a civil action to recover—

11 (1) such preliminary and equitable relief as the
12 court determines to be appropriate; and

13 (2) the greater of compensatory damages or liq-
14 uidated damages of \$5,000.

15 (b) PUNITIVE DAMAGES.—In any action brought
16 under this section in which the individual has prevailed
17 because of a knowing violation of a provision of this Act,
18 the court may, in addition to any relief awarded under
19 subsection (a), award such punitive damages as may be
20 warranted.

21 (c) ATTORNEY'S FEES.—In the case of a civil action
22 brought under subsection (a) in which the individual has
23 substantially prevailed, the court may assess against the
24 respondent a reasonable attorney's fee and other litigation

1 costs and expenses (including expert fees) reasonably in-
2 curred.

3 (d) LIMITATION.—No action may be commenced
4 under this section more than 3 years after the date on
5 which the violation was or should reasonably have been
6 discovered.

7 (e) AGENCY.—A principal is jointly and severally lia-
8 ble with the principal's agent for damages under this sec-
9 tion for the actions of the principal's agent acting within
10 the scope of the agency.

11 (f) ADDITIONAL REMEDIES.—The equitable relief or
12 damages that may be available under this section shall be
13 in addition to any other lawful remedy or award avail-
14 able.

15 **TITLE IV—MISCELLANEOUS**

16 **SEC. 401. RELATIONSHIP TO OTHER LAWS.**

17 (a) FEDERAL AND STATE LAWS.—Nothing in this
18 Act shall be construed as preempting, superseding, or re-
19 pealing, explicitly or implicitly, other Federal or State laws
20 or regulations relating to protected health information or
21 relating to an individual's access to protected health infor-
22 mation or health care services, if such laws or regulations
23 provide protections for the rights of individuals to the pri-
24 vacy of, and access to, their health information that are
25 greater than those provided for in this Act.

1 (b) PRIVILEGES.—Nothing in this Act shall be con-
2 strued to preempt or modify any provisions of State statu-
3 tory or common law to the extent that such law concerns
4 a privilege of a witness or person in a court of that State.
5 This Act shall not be construed to supersede or modify
6 any provision of Federal statutory or common law to the
7 extent such law concerns a privilege of a witness or person
8 in a court of the United States. Authorizations pursuant
9 to section 202 shall not be construed as a waiver of any
10 such privilege.

11 (c) CERTAIN DUTIES UNDER LAW.—Nothing in this
12 Act shall be construed to preempt, supersede, or modify
13 the operation of any State law that—

14 (1) provides for the reporting of vital statistics
15 such as birth or death information;

16 (2) requires the reporting of abuse or neglect
17 information about any individual;

18 (3) regulates the disclosure or reporting of in-
19 formation concerning an individual's mental health;
20 or

21 (4) governs a minor's rights to access protected
22 health information or health care services.

23 (d) FEDERAL PRIVACY ACT.—

1 (1) MEDICAL EXEMPTIONS.—Section 552a of
2 title 5, United States Code, is amended by adding
3 at the end the following:

4 “(w) CERTAIN PROTECTED HEALTH INFORMA-
5 TION.—The head of an agency that is a health care pro-
6 vider, health plan, health oversight agency, employer, in-
7 surer, health or life insurer, school or university, or person
8 who receives protected health information under section
9 204 of the Medical Information Privacy and Security Act
10 shall promulgate rules, in accordance with the require-
11 ments (including general notice) of subsections (b)(1),
12 (b)(2), (b)(3), (c), (e) of section 553 of this title, to ex-
13 empt a system of records within the agency, to the extent
14 that the system of records contains protected health infor-
15 mation (as defined in section 4 of such Act), from all pro-
16 visions of this section except subsections (b)(6), (d),
17 (e)(1), (e)(2), subparagraphs (A) through (C) and (E)
18 through (I) of subsection (e)(4), and subsections (e)(5),
19 (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), (r), and (u).”.

20 (2) TECHNICAL AMENDMENT.—Section
21 552a(f)(3) of title 5, United States Code, is amend-
22 ed by striking “pertaining to him,” and all that fol-
23 lows through the semicolon and inserting “pertain-
24 ing to the individual.”

1 (e) CONSTITUTION.—Nothing in this Act shall be
2 construed to alter, diminish, or otherwise weaken existing
3 legal standards under the Constitution regarding the con-
4 fidentiality of protected health information.

5 **SEC. 402. EFFECTIVE DATE.**

6 (a) EFFECTIVE DATE.—Unless specifically provided
7 for otherwise, this Act shall take effect on the date that
8 is 12 months after the date of the promulgation of the
9 regulations required under subsection (b), or 30 months
10 after the date of enactment of this Act, whichever is ear-
11 lier.

12 (b) REGULATIONS.—Not later than 12 months after
13 the date of enactment of this Act, or as specifically pro-
14 vided for otherwise, the Secretary shall promulgate regula-
15 tions implementing this Act.

○



CMS Library
C2-07-13
7500 Security Blvd.
Baltimore, Maryland 21244

CMS LIBRARY



3 8095 00010619 1